Remarks

The specification is amended herein to make reference to issued U.S. Patent No. 6,818,749 and to provide complete deposit information for the HuCC49V10 antibody.

Prior to this amendment, claims 1-43 were pending in this application (of which claims 28-35 and 38-41 were withdrawn). Claims 1-7, 9, 26, 37, 42, and 43 are amended herein. Claims 10-19 are canceled and new claims 44-50 are added. Of the withdrawn claims, claims 29 and 33 are amended to parallel the scope of the examined claims.

Claim 9 is amended to correct minor typographical errors. Support for the amendment of claims 1-7 can be found in the specification at least at page 35, lines 8-30; Figure 2; and the sequence listing. Support for the amendment of claims 1 and 37 can be found in the specification at least at page 31, lines 10-11. Support for the amendment of claim 26 (and withdrawn claims 29 and 33) can be found in the specification at least at page 20, line 30 through page 21, line 2l and page 60, lines 7-22. Support for the amendment of claims 42 and 43 can be found in the specification at least at page 31, lines 18-23, Figure 8, and the sequence listing. Support for new claims 44-47 can be found in the specification at least at page 17, lines 10-26. Support for new claims 48-49 can be found in the specification at least at page 13, lines 8-25 and for new claim 50 at page 41, lines 6-11.

No new matter has been added by these amendments. Applicants reserve the right to pursue canceled or deleted subject matter in a continuing application. Unless specifically stated otherwise, none of the amendments made herein are intended to limit the scope of any claim. After entry of this amendment **claims 1-9 and 20-50 are pending (of which claims 28-35 and 38-41 continue to be withdrawn)**. Reconsideration of the pending claims is respectfully requested.

Restriction Requirement

Applicants acknowledge that the election of Group I (claims 1-27, 36-37, and 42-43) is made final and that claims 28-35 and 38-42 are withdrawn.

Information Disclosure Statement

Applicants thank Examiner Blanchard for considering the references listed on the Information Disclosure Statement submitted on February 28, 2008.

Objections to the Specification

The specification is objected to because it discloses U.S. patent applications that are issued. The paragraphs beginning on page 20, line 14; page 30, line 25; page 31, line 12; and page 51, line 3 are amended to update the specification with the corresponding U.S. patent number. In view of the amendments to the specification, Applicants respectfully request that this objection be withdrawn.

Claim Objections

Claims 1 and 37 are objected to because they recite "humanized CC49 V10". As suggested by the Office action, claims 1 and 37 are amended to recite "huCC49V10".

Claim 9 is objected to because of a typographical error. Claim 9 is amended to recite "sequence set forth as".

Claim 26 is objected to as allegedly being an improper dependent claim for failing to further limit the subject matter of a previous claim. Claim 26 is amended to be in independent form.

In view of the amendments to the claims, Applicants respectfully request that the objections to claims 1, 9, 26, and 37 be withdrawn.

Claim Rejections Under 35 U.S.C. §112, second paragraph

Claims 1-27, 36-37, and 42-43 are rejected under 35 U.S.C. §112, second paragraph as allegedly "vague and indefinite in the recitation of "HuCC49V10" and "humanized CC49 V10" in claims 1 and 37 as the sole means of identifying the antibody" (Office action at page 4). Applicants respectfully disagree with this rejection. However, solely to advance prosecution in this application, claims 1 and 37 are amended to recite that the HuCC49V10 antibody was

deposited as ATCC Accession No. PTA-5416. Claims 2-9, 20-25, 27, 36, and 42-43 depend, directly or indirectly, from claim 1 and incorporate the limitations thereof. Claims 10-19 are canceled and claim 26 is amended to no longer refer to HuCC49V10, rendering the rejection of these claims moot.

Claims 1-25, 27, 36, and 42-43 are rejected as allegedly indefinite in the recitation of amino acid positions in claims 1-7, 10-18, and 42-43. Applicants respectfully disagree with this rejection. However, solely to advance prosecution in this case, claims 1-7 and 42-43 are amended to refer to positions of a reference sequence, as suggested by the Office action. Claims 27 and 36 depend from claim 1 and incorporate the limitations thereof. Claims 10-18 are canceled, rendering the rejection of these claims moot.

Claims 10-19 are rejected as allegedly indefinite "because it is unclear what is being referenced by the recitation 'wherein the light chain framework comprises SEQ ID NO:X…' and 'wherein the heavy chain framework comprises SEQ ID NO:Y…'." (Office action at page 4). As discussed above, claims 10-19 are canceled, rendering this rejection of these claims moot.

In view of the amendments to the claims, Applicants respectfully request that the objections to claims 1-27, 36-37, and 42-43 be withdrawn.

Claim Rejections Under 35 U.S.C. §112, first paragraph

Claims 1-27, 36-37, and 42-43 are rejected under 35 U.S.C. §112, first paragraph, as allegedly the specification is not enabling because it is "unclear if a cell line, which produces an antibody having the exact chemical identity of antibody HuCC49V10 antibody (ATCC accession no. PTA-5416) is known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore a suitable deposit for patent purposes is suggested" (Office action at page 5).

Attached, as **Exhibit A**, is a deposit receipt from the American Type Culture Collection, which acknowledge that a deposit of HuCC49V10 was made in accordance with the Budapest Treaty. Exhibit A identifies HuCC49V10, deposited as ATCC Accession No. PTA-5416 on

August 28, 2003. Thus, the HuCC49V10 antibody is known and readily available to the public, and reproducible without undue experimentation. All restrictions on public access to ATCC Accession No. PTA-5416 are irrevocably removed upon the grant of a patent, in accordance with the Budapest Treaty. In light of the above statements, the deposits, and the attached receipts, Applicants submit that all the conditions of 37 C.F.R 1.801-1.809 have been met.

As requested in the Office action, the specification is amended herein to provide complete deposit information by reciting the date of deposit and the complete name and address of the depository.

Reconsideration and withdrawal of this rejection of claims 1-27, 36-37, and 42-43 are respectfully requested.

Claim Rejections Under 35 U.S.C. §102

Claims 1-19 are rejected under 35 U.S.C. §102(a) as allegedly anticipated by Gonzales *et al.* (*Proceedings of the American Association for Cancer Research,* Annual meeting, vol. 44, page 1118, 2003[a]) as evidenced by Gonzales *et al.* (*Molecular Immunology,* 40(6):337-349, 2003[b]).

Applicants submit herewith evidence in the form of a Declaration under 37 C.F.R. §1.132 to overcome Gonzales *et al.* The Declaration states that co-authors Eduardo A. Padlan, Jeffrey Schlom, and Syed V.S. Kashmiri are inventors of the subject matter claimed in the present application. The Declaration also states that the remaining co-authors, Noreen R. Gonzales, Roberto De Pascalis, and Peter Schuck are not inventors of the present application. Thus, Gonzales *et al.* is a disclosure made by the applicants themselves. As such, this reference does not satisfy the requirement of §102(a), which requires an anticipatory disclosure be made "before the invention thereof by the applicant." In view of the Declaration Under 37 C.F.R. §1.132, Gonzales *et al.* is not available as prior art. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. §103(a)

Claims 1-25, 27, and 36 are rejected under 35 U.S.C. §103(a) as allegedly being obvious in light of Gonzales *et al.* (2003[a]), as evidenced by Gonzales *et al.* (2003[b]), in combination with Kashmiri *et al.* (WO 00/26394, published May 11, 2000). Applicants respectfully traverse this rejection.

As discussed above, Gonzales *et al.* 2003[a] is not available as prior art against the current application. The secondary reference, WO 00/26394, does not teach all the limitations of the claims.[1] WO 00/26394 discloses the HuCC49V10 antibody (variant $^{97}L_{1,2}/^{60\text{-}62,\ 64}H$). However, WO 00/26394 does not disclose the residue substitutions of the claimed antibodies. Thus, WO 00/26394 alone does not anticipate claims 1-25, 27, and 36. Moreover, WO 00/26394 teaches that the murine framework residues (including those at Kabat positions 5, 19, 21, 43, 78, 100, and 106 of the light chain, and 12, 20, 38, 40, 48, 66, 67, 69, and 80 of the heavy chain) are required for maintaining the integrity of the antigen combining site. As the claimed antibodies (variants of HuCC49V10) having substitutions at these positions retain binding affinity for TAG-72, compared to HuCC49V10, WO 00/26394 *teaches away* from making such substitutions. Thus, WO 00/26394 does not render these claims obvious. In light of the above discussion, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 1-25, 27, and 36.

Claims 1 and 42-43 are rejected under 35 U.S.C. §103(a) as allegedly being obvious in light of Gonzales *et al.* (2003[a]), as evidenced by Gonzales *et al.* (2003[b]), in combination with Gonzales *et al.* (*Proceedings of the American Association for Cancer Research,* Annual meeting, vol. 44, page 1116, July 2003[c]) as evidenced by De Pascalis *et al.* (*Clinical Cancer Research*, 9:5521-5531, 2003).[2] Applicants respectfully traverse this rejection.

[1] Gonzales *et al.* 2003[b] was published after the priority date of this application and is not prior art.

[2] We note that Gonzales *et al.* pp. 1116, 2003[c] is, in fact, De Pascalis *et al.*, pp. 1115-1116, 2003. Thus, we will refer to this reference as De Pascalis *et al.* (2003[a]) and the second De Pascalis *et al.* reference (*Clinical Cancer Research*, 9:5521-5531, 2003) as De Pascalis *et al.* (2003[b]). De Pasclalis *et al.* 2003[b] was published after the priority date of this application and is not prior art.

As discussed above, Gonzales *et al.* 2003[a] is not available as prior art against the current application. The secondary reference, De Pascalis *et al.* (2003[a]), does not disclose the murine framework residue substitutions of the claimed antibodies and therefore does not teach all the limitations of the claims. Thus, De Pascalis *et al.* alone does not anticipate or render obvious claims 1 and 42-43. In light of the above discussion, Applicants respectfully request reconsideration and withdrawal of this rejection of claims 1 and 42-43.

Nonstatutory obviousness-type double-patenting

Claims 1-22, 24-27, and 36-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-47 of U.S. Patent No. 6,818,749 (Kashmiri *et al.*; issued U.S. national stage patent of WO 00/26394, cited in rejection under 35 U.S.C. §103, above) in view of Gonzales *et al.* (2003[a]), as evidenced by Gonzales *et al.* (2003[b]) because allegedly the conflicting claims are not patentably distinct from each other. Specifically, the Office alleges that "it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced humanized CC49 antibody variant 59 and antigen-binding fragments thereof (e.g., Fv, Fab, Fab', F(ab')2) linked to a diagnostic or therapeutic agent (e.g., a radionuclide) and kits and pharmaceutical compositions comprising variant 59 and a pharmaceutically acceptable carrier for therapeutic benefit in human carcinoma patients" (Office action at page 16). Applicants respectfully traverse this rejection.

As discussed above, Gonzales *et al.* 2003[a] is not available as prior art against the current application. Also as discussed above, WO 00/26394 (issued as U.S. Patent No. 6,818,749) does not teach the claimed residue substitutions and, in fact, *teaches away* from substituting the murine framework residues. Thus, contrary to the assertion of the Office (see Office action at page 16), Applicants submit that the prior art would not have provided a motivation or reasonable expectation of success to have produced the claimed antibodies, antigen-binding fragments thereof, and kits and pharmaceutical compositions thereof, based on the teachings of the cited references. Accordingly, U.S. Patent No. 6,818,749 does not render the claims of the subject application obvious and Applicants submit that the claimed antibodies are patentably distinct from claims 1-47 of U.S. Patent No. 6,818,749.

In view of the above amendments, Applicants request reconsideration and withdrawal of the provisional nonstatutory obviousness-type double patenting rejection based on the cited prior art references.

Request for Rejoinder

The Examiner has required a restriction between product and process claims. The Applicants have elected claims to a specific product. In accordance with M.P.E.P. § 821.04, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. Applicants expressly request that the method claims be rejoined and the claims examined, at the latest upon the allowance of any of the product claims. It is believed that this is in accordance with the current Patent and Trademark Office Guidelines for Restriction Requirements in TC1600.

Conclusion

If any matters remain to be addressed before a Notice of Allowance is issued, the Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By /Anne Carlson/
Anne Carlson, Ph.D.
Registration No. 47,472